



# **ATTACHMENT E**



Patents Office  
45 Merrion Square  
Dublin 2

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

|                 |  |
|-----------------|--|
| Application No. | 930649   |
| Date of filing  | 6 September 1993   |
| Applicant       | PATRICK LEAHY an Irish citizen, of Apartment 9, The Elms, Mount Merrion Avenue, Blackrock, County Dublin, Ireland, and FRANK BONADIO a U.S. citizen, of 2 Martello Terrace, Bray, County Wicklow, Ireland. |

RIBBON CUT BY  
CERTIFICATION BRANCH

Dated this 5<sup>th</sup> day of June, 1998

An officer authorised by the  
Controller of Patents, Designs and Trademarks.

BEST AVAILABLE COPY

## REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☒

the grant of a patent under Part II of the Act

☐

the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name 1. PATRICK LEAHY

2. FRANK BONADIO

2 Martello Terrace,  
Bray,  
County Wicklow,  
Ireland.

Address

Apartment 9, The Elms,  
Mount Merrion Avenue,  
Blackrock, County Dublin, Ireland.

Description/Nationality

an Irish Citizen

a U.S. Citizen

2. Title of Invention

"Apparatus for use in surgery"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date

Country in or for which filed

Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

Address

PATRICK LEAHY,  
an Irish Citizen  
Apartment 9,  
The Elms,  
Mount Merrion Avenue,  
Blackrock,  
County Dublin,  
Ireland.

Frank Bonadio,  
a U.S. Citizen of  
2 Martello Terrace,  
Bray,  
County Wicklow,  
Ireland.

CONTINUED OVER

5. Statement of right to be granted a patent (Section 17(2)(b))

Not Applicable

6. Items accompanying this Request - tick as appropriate

- (i) ☒ prescribed filing fee (£117 )
- (ii) ☒ specification containing a description and claims
- ☐ specification containing a description only
- ☒ Drawings referred to in description or claims
- (iii) ☐ An abstract
- (iv) ☐ Copy of previous application(s) whose priority is claimed
- (v) ☐ Translation of previous application whose priority is claimed
- (vi) ☒ Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No: .....  
Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name

CRUICKSHANK & CO.,

Address

1 Holles Street,  
Dublin 2,  
Ireland.

9. Address for Service (if different from that at 8)

CRUICKSHANK & CO., at their address recorded for the time being in the Register of Patent Agents is hereby appointed Agents and address for service.

Signed

Name(s):

BY

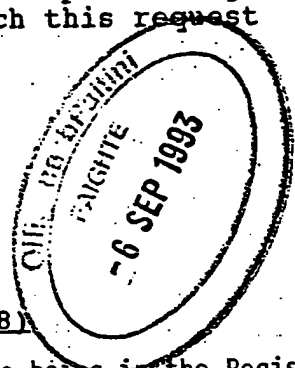
CRUICKSHANK & CO.,

EXECUTIVE

Capacity (if applicant is a body corporate):

Agents for the Applicant

Date September 6, 1993



"Apparatus for Use in Surgery"

The invention relates to an apparatus for use in surgery and in particular to an apparatus to be used in minimal invasive surgery in which surgery is carried out by making the minimum number of incisions in a patient's body.

5 Abdominal surgery is generally carried out by making a very large incision allowing a surgeon to enter the body cavity with both hands. Such surgery is traumatic for the patient and the healing process is lengthy. Some laproscopic surgery such as hernia operations may be  
10 carried out by surgeons using minimal invasive techniques with trocar assemblies. However, the techniques are generally complex and difficult and are not widely used.

According to the invention there is provided an apparatus for use in surgery comprising a sleeve having an entry  
15 opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body, exit sealing means being provided for sealing the exit opening to a body and entry sealing means being provided for sealing the outer entry gainst an arm passing therethrough to  
20 create a controlled environment within the sleeve.

In a particularly preferred embodiment of the invention the sleeve is of a flexible material. Most preferably, the sleeve is of a gas-impermeable material to create a controlled pressurised environment within the sleeve.

25 In a particularly preferred embodiment of the invention the sleeve comprises a generally cylindrical body closed at one end thereof and an exit opening is provided in a side wall of a body adjacent the closed end.

In one arrangement the exit sealing means comprises a flange around the exit for sealing against the body of a patient. Preferably the flange is provided with an adhesive for adhering to the body. Typically the exit and  
5 flange are covered by a peel-off cover.

In another arrangement the flange is engaged with a mounting ring surrounding an incision in a patient's body.

The entry sealing means may comprise a valve means through which a surgeon passes an arm. Preferably the valve means  
10 is of a material which is sufficiently flexible to allow an arm to be passed therethrough and to seal against the arm when passed therethrough.

Alternatively, the means comprises a first mounting in the sleeve entry, a second mounting and a sealing body of  
15 flexible material extending between the mountings, one of the mountings being twisted relative to the other two to twist the sealing body into engagement with an arm passing therethrough.

In one arrangement fixing means are provided for fixing  
20 one mounting relative to the other in the sealing position. Typically the fixing means comprises inter-engaging formations provided on the mountings.

In another arrangement the first mounting comprises a ring mounted in the sleeve at the entry thereof.

25 In a particularly preferred arrangement the second mounting comprises a ring to which the sealing material is attached.

In one embodiment of the invention the entry sealing means comprises a first sealing element provided in the entry

and a second sealing entry provided on a surgical glove, the sealing elements inter-engaging to seal the sleeve on passing of the glove through the entry.

5 The invention will be more clearly understood from the following description thereof, given by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a plan view of a sleeve;

10 Fig. 2 is a cross-sectional view of the sleeve of Fig. 1;

Fig. 3 is a plan view of a sleeve with an entry sealing means in position;

Fig. 4 is a perspective view of the sleeve of Fig. 3 in use;

15 Fig. 5 is a perspective view of the entry sealing means used in the sleeve of Figs. 3 and 4 in an open configuration;

Fig. 6 is a side elevational view of the sealing means of Fig. 5 in an intermediate position;

20 Fig. 7 is a perspective view of the sealing means of Fig. 5 in a sealed configuration;

Fig. 8 is a perspective view of another sleeve according to the invention; and

25 Fig. 9 is a side cross-sectional view of a further sleeve according to the invention.

Referring to the drawings and initially to Figs. 1 to 7 thereof, there is illustrated an apparatus for use in surgery according to the invention indicated generally by the reference numeral 1. The apparatus 1 comprises a sleeve 2 of flexible gas-impermeable material. The sleeve 2 in this case comprises a generally cylindrical body closed at one end 3 thereof and open at the other end 4 thereof to define an entry opening at an outer end for passage of an instrument and/or surgeon's arm. An exit opening 5 is provided in a side wall of the sleeve 2 as illustrated particularly in Fig. 2 to provide an access point for entering a patient's body through an incision therein.

Exit sealing means 10 for sealing the exit opening 5 to a patient's body is in this case provided by a flange 11 around the exit opening 5 to the outer face of which is applied a pressure sensitive adhesive for adhering to the body of the patient. The adhesive side of the flange 11 is covered prior to use with a peel-off cover 12.

Entry sealing means which for clarity is not illustrated in Figs. 1 and 2 is in this case provided by a valve means indicated generally by the reference numeral 20 and illustrated particularly in Figs. 3 to 7. The valve means 20 comprises a first mounting provided by a ring 21 attached to the body of the sleeve 2 at the entry 4 and a second mounting provided by another ring 22 which is attached to the first ring 21 by a sealing member 23 of flexible material extending between the rings.

The outer ring 22 with the flexible body 23 attached is rotated to twist the sealing body 23 in the direction of the arrow X illustrated in Fig. 6 to engage and seal against a surgeon's arm 30 passing therethrough. When the sealing member 23 is in sealing engagement the outer ring



22 is pushed forwardly in the direction of the arrow Y against the inner ring 21 and the rings are engaged together to maintain the sealing engagement.

5 Fixing means for preventing rotation of the rings 21, 22 relative to one another when the rings are in the sealing position illustrated in Fig. 7 is in this case provided by a plurality of projections 27 on one of the rings 22 which are engageable with a plurality of complimentary shaped recesses 28 in the other rings 21 to lock the rings 21, 22  
10 against rotation in the sealing position.

In use, an incision is first made in a patient 31. The cover 11 is then removed and the flange 12 is adhesively bonded to the patient around the incision as illustrated particularly in Fig. 4. The sleeve is arranged so that  
15 the exit opening 5 is aligned with the incision in the patient 31. With the entry sealing means 20 in the open non-sealing configuration illustrated in Figs. 3 and 5 a surgeon passes his hand and arm 30 through the entry 4 and the exit opening 5 to enter the patient's body through the  
20 incision. When the surgeon's arm 30 has passed through the sealing means 20 a desired distance, the outer ring 22 with the sealing body 23 attached is rotated to twist the sealing body 23 to engage against the surgeon's arm 30 until a relatively tight seal is obtained. The ring 22 is  
25 then pushed forwardly against the ring 21 and the projections are engaged in the recesses 28 to lock the rings 21, 22 together against rotation in the sealing configuration. In the case of bowel re-section surgery, gas is pumped into the patient's body cavity where the  
30 surgery is to be performed, the gas exiting through the incision in the patient and the opening 5 into the sleeve 2 to create a controlled pressurised environment in the sleeve 2 in which the sleeve 2 is inflated. The surgeon carries out the surgery as required and when completed the

ring 22 is released from the ring 21 and contra-rotated until the flexible body 23 is in the non sealing position allowing the surgeon to extract his hand through the sleeve 2.

5 There are many advantages of the invention. Because a surgeon need only make a relatively small incision the trauma to the patient is minimised, there is less risk of damage to the immune system and the healing time is short with a consequent decrease in the length of the hospital  
10 stay required. The techniques are considerably simpler than conventional laproscopic surgical techniques and can be readily performed by a surgeon with minimal additional training. A wide range of operations can be performed using the apparatus of the invention.

15 Referring to Fig. 8 there is illustrated another apparatus for use in surgery according to the invention indicated generally by the reference numeral 50. The apparatus 50 is similar to the apparatus described above with reference to Figs. 1 to 4 and like parts are assigned the same  
20 reference numerals. In this case the entry sealing means comprises a first ring 51 mounted to the sleeve 2 at the entry 4 and a second separate ring 52 at the free end of a surgical glove 53. When a surgeon's arm with the glove 53 passes through the entry 5 the rings 51, 52 are  
25 arranged to sealingly engage to create a controlled environment within the sleeve 2 during an operation.

Referring to Fig. 9 there is illustrated a further apparatus according to the invention for use in surgery and indicated generally by the reference numeral 60. In  
30 this case, the exit sealing means comprises a sealing diaphragm having a first ring 61 attached to the sleeve 2 and a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted

through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurised environment in the sleeve 5 2.

It is anticipated that in some cases adhesive may be applied to a patient around the area of an incision to which a sealing ring of the sleeve is to be attached during preparations for an operation. Adhesive may 10 alternatively or additionally be applied to the ring to be attached around the area of an incision. Either or both layers of adhesive may be covered by a sterile wrapping material through which the incision may be made. Either or both layers of adhesive may be provided with peel off 15 covers.

It will further be appreciated that the sleeve may incorporate an air lock to facilitate changing of an instrument and/or debris such as cancer cells during an operation without breaking the sterilised environment in 20 the sleeve.

The sleeve may be provided with more than one inlet opening for a surgeon's arms and/or instruments.

The sleeve may also be provided with means to create an intermediate pressurised environment by, for example, 25 providing two inlet sealing cuffs spaced-apart along the sleeve. The inner of the cuffs being sealed before the seal provided by the outer cuff is opened.

Many variations on the specific embodiments of the invention described will be readily apparent and 30 accordingly the invention is not limited to the embodiments hereinbefore described, but may be varied in construction and detail.

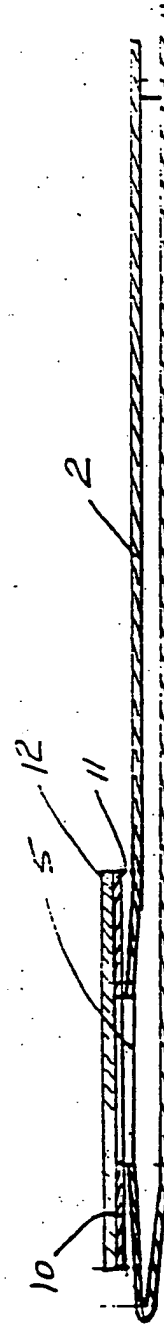
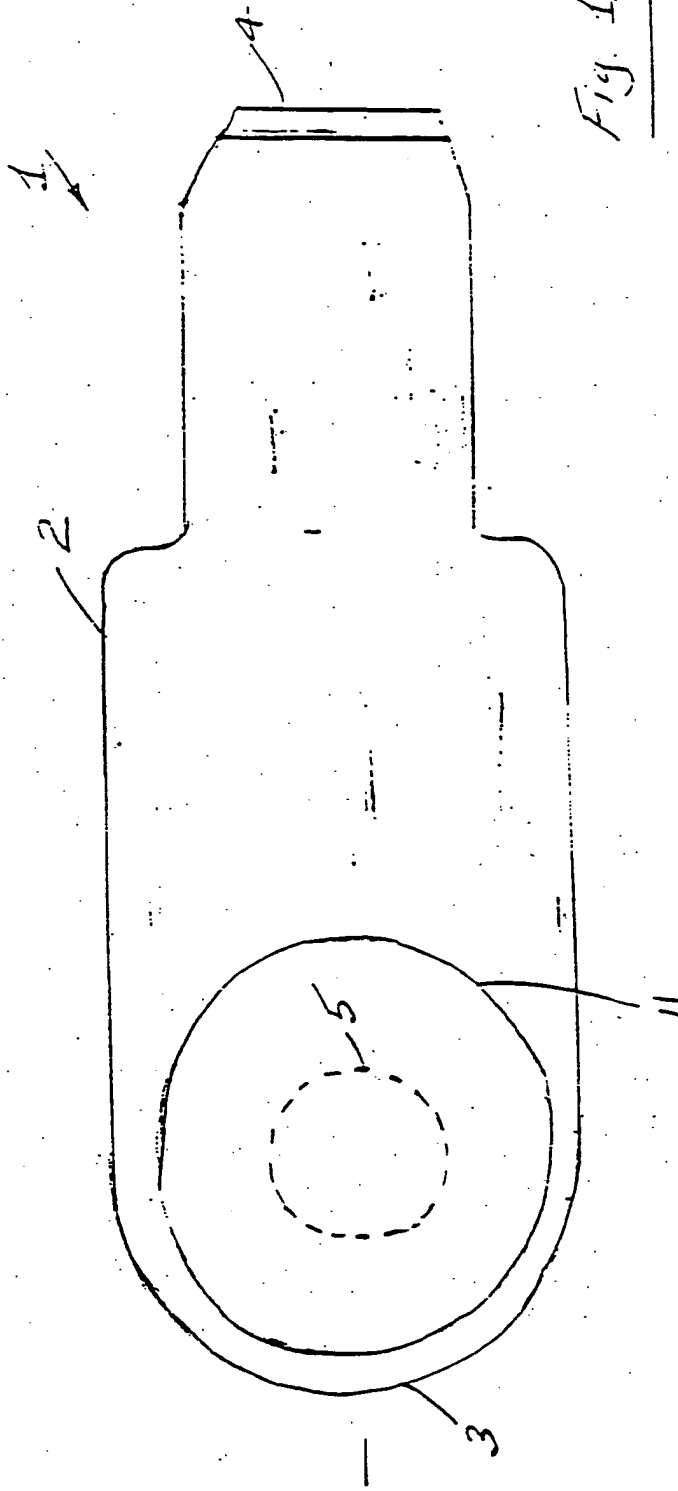
CLAIMS:

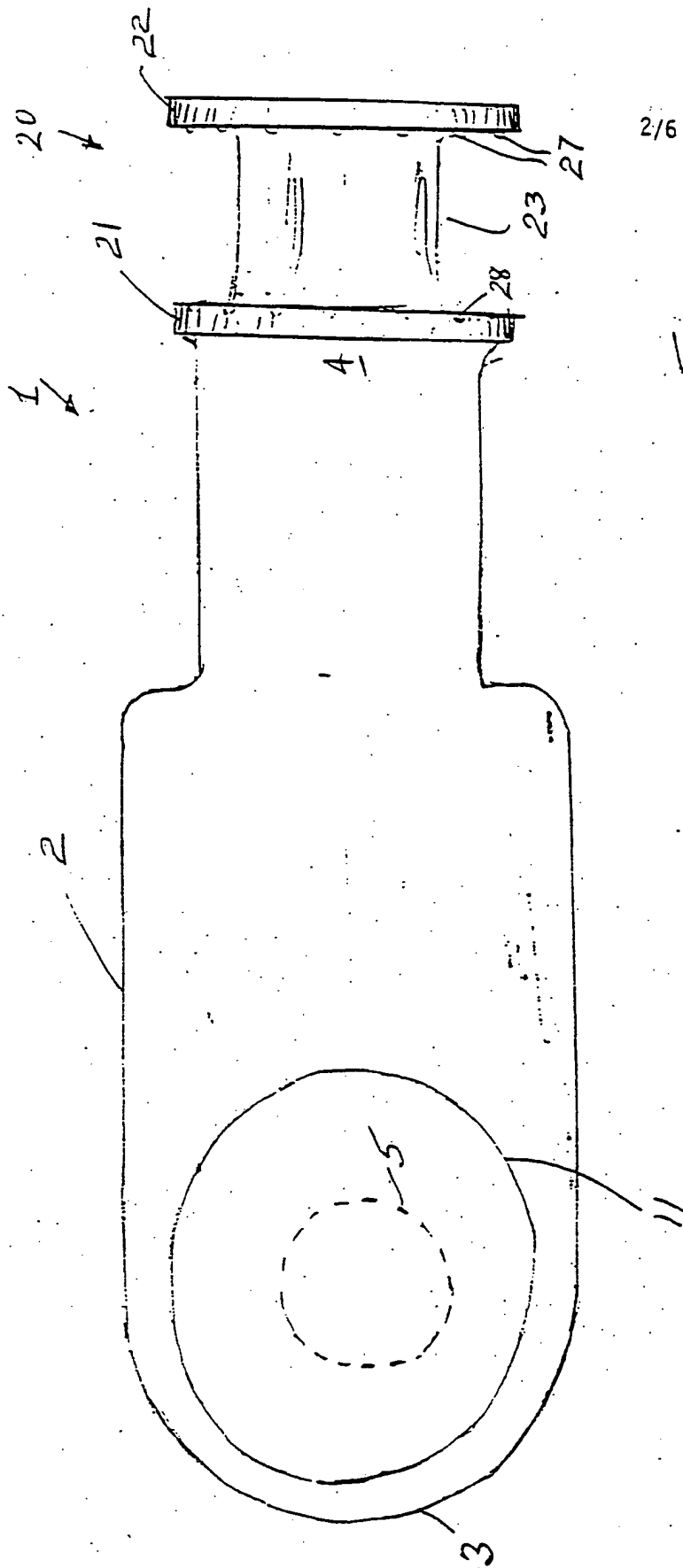
1. Apparatus for use in surgery comprising a sleeve having an entry opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body, exit sealing means being provided for sealing the exit opening to a body and entry sealing means being provided for sealing the outer entry against an arm passing therethrough to create a controlled environment within the sleeve.
2. Apparatus as claimed in Claim 1 wherein the sleeve is of a flexible material.
3. Apparatus as claimed in Claim 1 or 2 wherein the sleeve is of a gas-impermeable material to create controlled pressurised environment within the sleeve.
4. Apparatus as claimed in any preceding claim wherein the sleeve comprises a generally cylindrical body closed at one end thereof and an exit opening is provided in a side wall of a body adjacent the closed end.
5. Apparatus as claimed in any preceding claim wherein the exit sealing means comprises a flange around the exit for sealing against the body of a patient.
6. Apparatus as claimed in Claim 5 wherein the flange is provided with an adhesive for adhering to the body.

7. Apparatus as claimed in Claim 5 or 6 wherein the exit and flange are covered by a peel-off cover.
8. Apparatus as claimed in Claim 5 wherein the flange is engaged with a mounting ring surrounding an incision in a patient's body.
9. Apparatus as claimed in any preceding claim wherein the entry sealing means comprises a valve means through which a surgeon passes an arm.
10. Apparatus as claimed in Claim 9 wherein the valve means is of a material which is sufficiently flexible to allow an arm to be passed therethrough and to seal against the arm when passed therethrough.
11. Apparatus as claimed in Claim 9 wherein the valve means comprises a first mounting in the sleeve entry, a second mounting and a sealing body of flexible material extending between the mountings, one of the mountings being twisted relative to the other to twist the sealing body into engagement with an arm passing therethrough.
12. Apparatus as claimed in Claim 11 wherein fixing means are provided for fixing one mounting relative to the other in the sealing position.
13. Apparatus as claimed in Claim 12 wherein the fixing means comprises inter-engaging formations provided on the mountings.
14. Apparatus as claimed in any of Claims 11 to 13 wherein the first mounting comprises a ring mounted in the sleeve at the entry thereof.

15. Apparatus as claimed in Claim 14 wherein the second mounting comprises a ring to which the sealing material is attached.
- 5 16. Apparatus as claimed in any of Claims 1 to 8 wherein the entry sealing means comprises a first sealing element provided in the entry and a second sealing entry provided on a surgical glove, the sealing elements inter-engaging to seal the sleeve on passing of the glove through the entry.
- 10 17. Apparatus substantially as hereinbefore described with reference to the accompanying drawings.

CRUICKSHANK & CO.,





2/6

Fig. 3



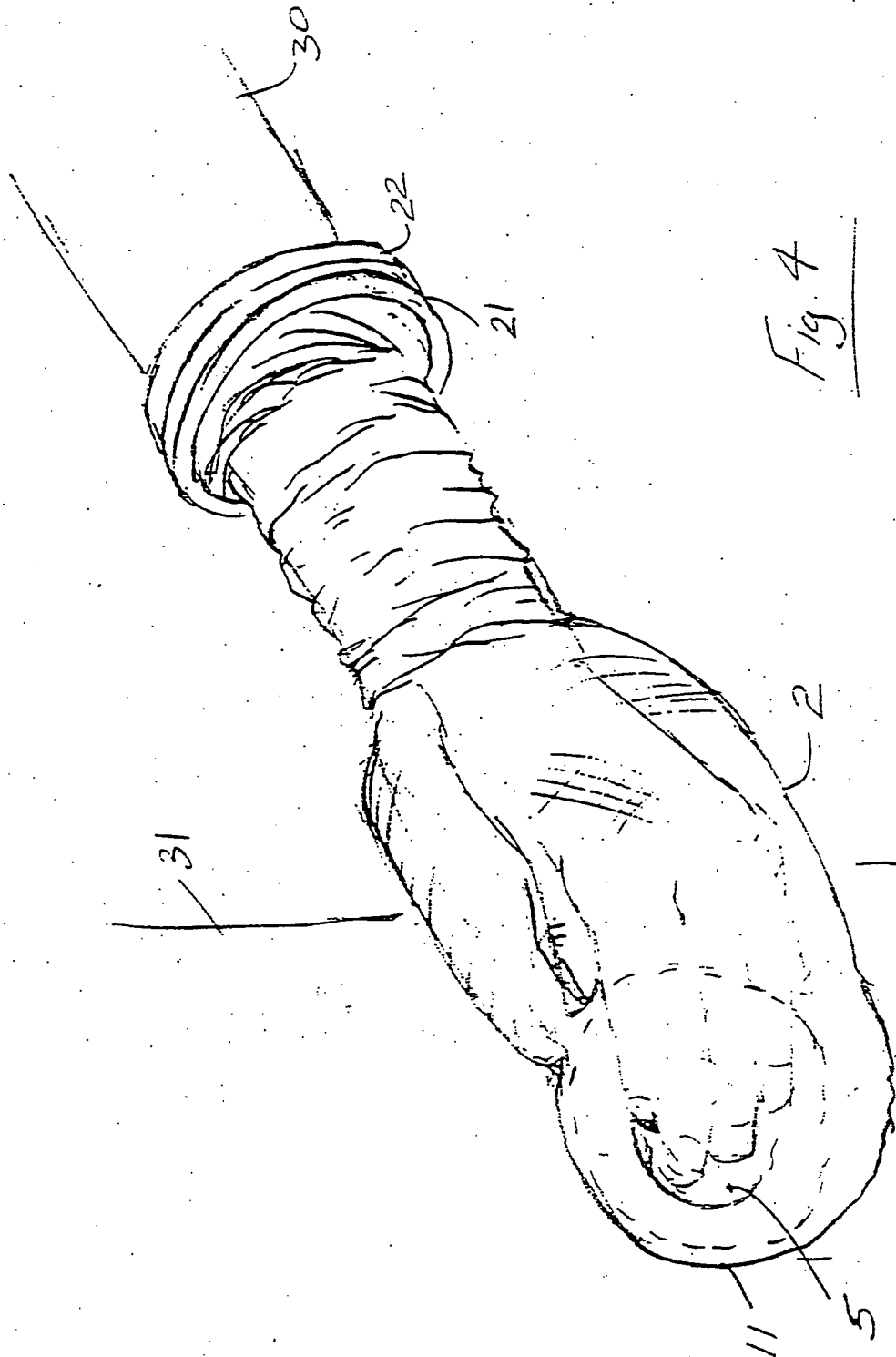


Fig. 4

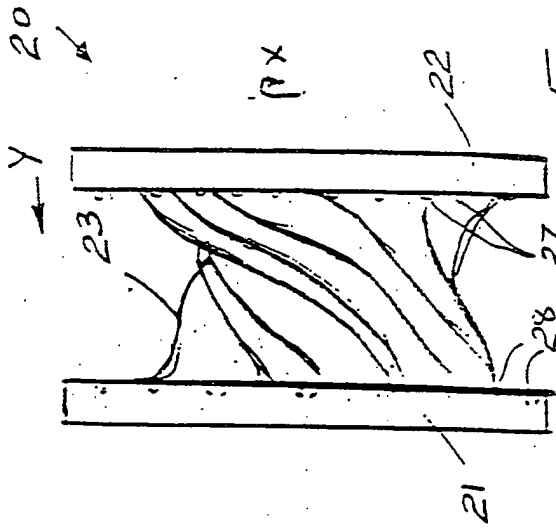


Fig. 6

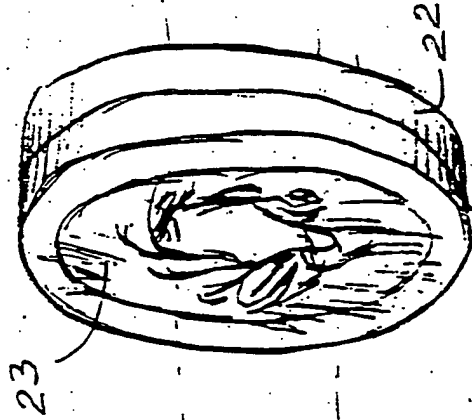


Fig. 7

20

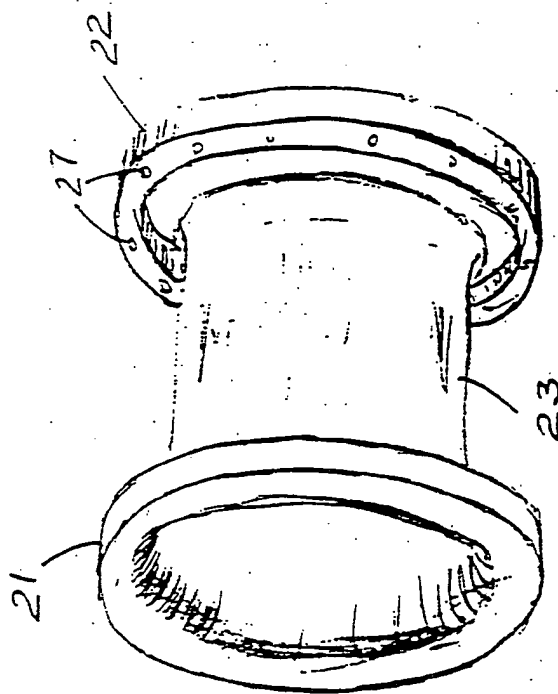


Fig. 5

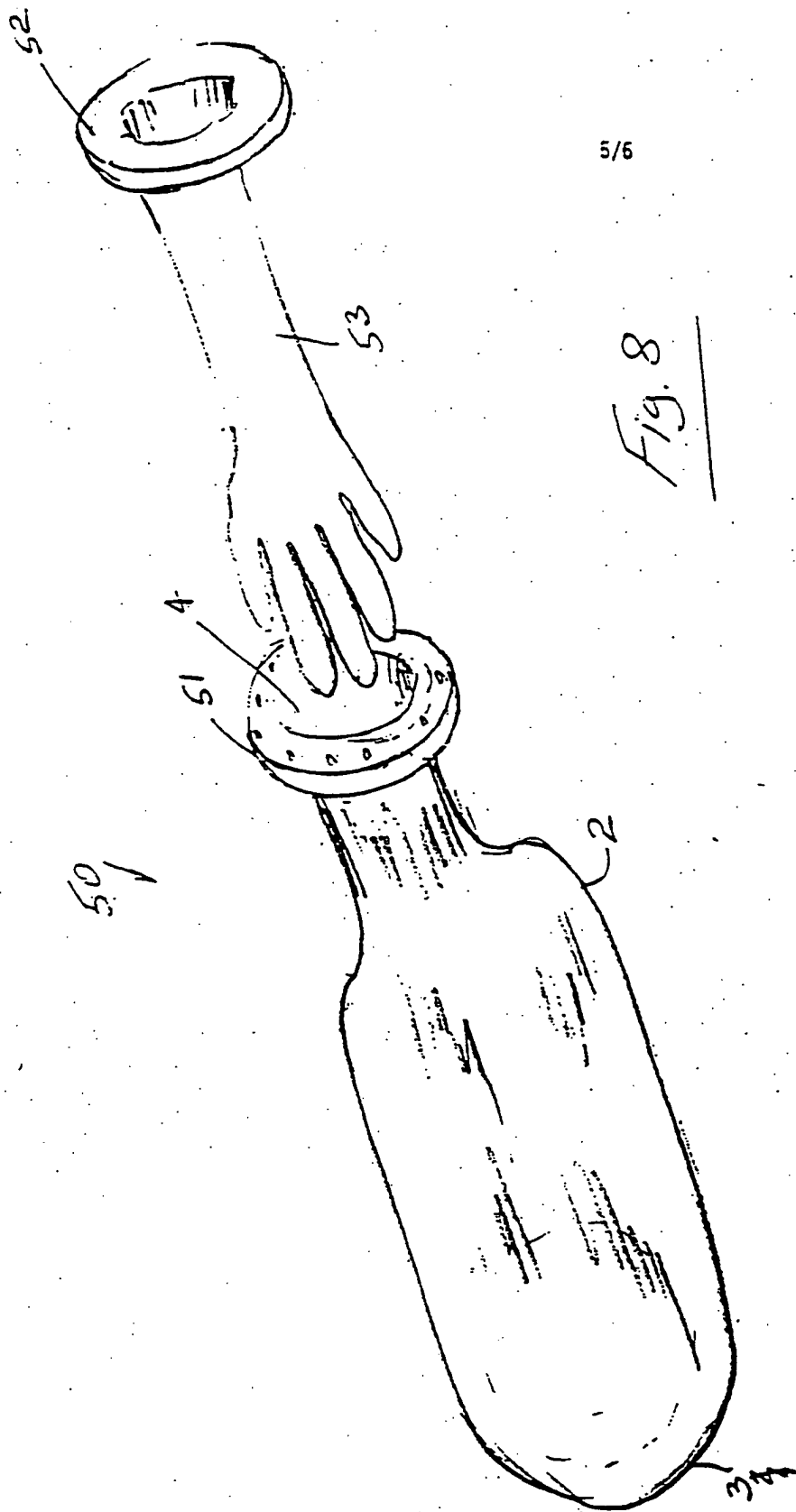


Fig. 8

60

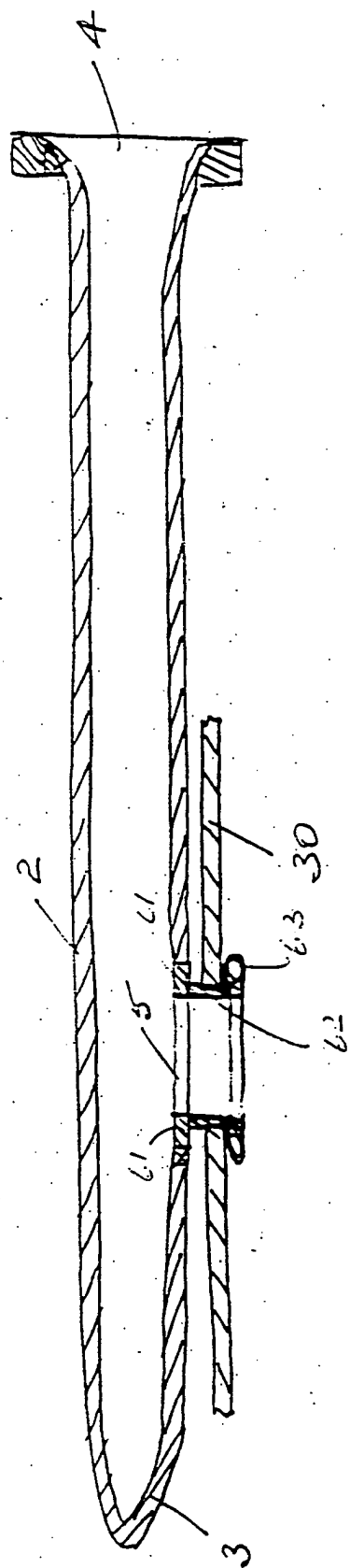


Fig. 9

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☒ FADED TEXT OR DRAWING

☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**